

INPLASY

Effectiveness and impact of rotavirus vaccination, real-world study: a systematic review

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Yu, F; Cao, J; Furuya Kanamori, L; Kiani, B; Lau, CL; Sartorius, B.

Corresponding author:

Benn Sartorius

b.sartorius@uq.edu.au

Author Affiliation:

The University of Queensland.

ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 March 2025 and was last updated on 12 March 2025.

INTRODUCTION

Review question / Objective To understand the effectiveness and impact of rotavirus vaccination globally, and compare the effectiveness and impact by different population characteristics, vaccines and different countries based on extracted data from included articles.

Condition being studied Rotavirus is globally recognized as a leading cause of acute gastroenteritis in young children. The rotavirus vaccine is an effective preventive measure that significantly reduces the incidence and severity of rotavirus infections since 2006. It is included in many national immunization programs and has led to substantial declines in hospitalizations and mortality among children. However, as rotavirus vaccine is introduced in more countries, some region using new rotavirus vaccine and previous studies based on limited data of Asian countries and low-income countries, the effectiveness and

impact of rotavirus vaccines should be further understood.

METHODS

Participant or population All aged population, normally children under 5 years old.

Intervention Rotavirus vaccines.

Comparator No vaccination.

Study designs to be included Clinical trials (RCT), real-world effectiveness studies (epidemiological research, medical care data, surveillance data), cohort, case control studies, original study with large dataset, observational studies.

Eligibility criteria Inclusion criteria:

1. Clinical trials (RCT), real-world effectiveness studies (epidemiological research, medical care data, surveillance data), cohort, case control study,

original study with large dataset, observational studies published in any languages.

2. Vaccine effectiveness reported by vaccine types, usually reported as Odds Ratio (OR), Risk Reduction (RR) ; reduction of outcomes, like incidence, hospitalization, death reported by vaccine types.

3. Rotavirus gastroenteritis should be confirmed by laboratory detection methods.

Exclusion criteria:

1. No any VE estimates or related outcomes.
2. Case reports, animal studies.
3. Review or meta-analysis articles.
4. Not available for full-text and data couldn't be collected from the abstract.

Information sources

Database 1: PubMed

Database 2: Web of science

Database 3: Scopus

Database 4: Embase (non-english, optional)

Database 5: Cochrane

Database 6: CNKI

Database 7: WANFANG.

Main outcome(s) 1. Vaccine Effectiveness (%); 2. Reduction in rotavirus gastroenteritis cases, hospitalizations, deaths and so on.

Quality assessment / Risk of bias analysis

Article screening and full-text review will be conducted by 2 reviewers with Covidence. Disagreement will be resolved by the third expert. If applicable, Newcastle-Ottawa Scales (NOS) will be used to assess the quality of observational study. Publication bias will be assessed using funnel plots of the standard error, sampling variance, and the inverse of the standard error and sampling variance.

Strategy of data synthesis Study characteristics (design, population, vaccine type, country, follow-up duration), key findings on vaccine effectiveness (VE) and outcome measures will be extracted for descriptive analysis. If applicable, will conduct meta-analysis using fixed-effects model or random-effects model to further quantify the results, the heterogeneity will be assessed.

Subgroup analysis Will compare the main outcomes, the effectiveness of rotavirus vaccines and impact by age, gender, country, type of vaccine.

Sensitivity analysis The main outcome will be analyzed by subgroup, like the age, sex, region and vaccine type. For meta-analysis will use leave-

one-out analysis to check if one study is disproportionately affecting the overall findings.

Language restriction Any language.

Country(ies) involved Australia, China.

Keywords Rotavirus; Vaccination; Effectiveness; Impact.

Contributions of each author

Author 1 - Fan Yu.

Email: fan.yu@uq.edu.au

Author 2 - Jin Cao.

Email: jin.cao@uq.edu.au

Author 3 - Luis Furuya Kanamori.

Email: l.furuya@uq.edu.au

Author 4 - Behzad Kiani.

Email: b.kiani@uq.edu.au

Author 5 - Colleen Lau.

Email: colleen.lau@uq.edu.au

Author 6 - Benn Sartorius.

Email: b.sartorius@uq.edu.au